

**REMARKS/ARGUMENTS**

Claims 1-12 and 27-35 are pending in this Application.

Claims 1-3, 5, 7, 10, and 34 are currently amended. Applicants submit that support for the claim amendments can be found throughout the specification and the drawings.

Claims 1-12 and 27-35 remain pending in the Application after entry of this Amendment. No new matter has been entered.

In the Office Action, claims 1, 2, 4, 5, 8-12, 27, 28, 30, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over non-patent literature entitled "Stability Lab Information Manager" (hereinafter "SLIM") in view non-patent literature entitled "Stability System 2000" (hereinafter "Stability"). Claims 3 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over SLIM, in view of Stability, and in further view of U.S. Patent No. 6,167,523 (hereinafter "Strong"). Claims 6, 7, 32, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over SLIM, in view of Stability, and in further view of U.S. Patent Publication No. 2002/0133395 (hereinafter "Hughes").

**Claim Rejections Under 35 U.S.C. § 103(a)**

Applicants respectfully traverse the rejections to claims 1-12 and 27-35 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) based on SLIM, Stability, Strong, and Hughes. The Office Action alleges that claimed invention is directed to obvious subject matter, in that the combination of SLIM, Stability, Strong, and Hughes expressly or impliedly disclose or suggest the claimed invention. The Office Action further alleges that one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of SLIM, Stability, Strong, and Hughes.

Applicants, however, respectfully submit that a prima facie case of obviousness has not been established by the evidence presented in the Office Action. As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007), the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). The factual inquiries enunciated by the Court are as follows:

(A) Determining the scope and content of the prior art;

(B) Ascertaining the differences between the claimed invention and the prior art;

and

(C) Resolving the level of ordinary skill in the pertinent art.

To reach a proper determination under 35 U.S.C. § 103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the Examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. (M.P.E.P. § 2142).

Applicants respectfully submit that SLIM, Stability, Strong, and Hughes, either individually or in combination, fail to disclose one or more of the claim limitations recited in each of claims 1-12 and 27-35. These differences, along with other difference, establish that the subject matter as a whole of claims 1-12 and 27-35 would not have been obvious at the time of invention to a person of ordinary skill in the art.

In determining the scope and content of the prior art, Office personnel must first obtain a thorough understanding of the invention disclosed and claimed in the application under examination by reading the specification, including the claims, to understand what the applicant has invented. (See M.P.E.P. § 904.) The scope of the claimed invention must be clearly determined by giving the claims the “broadest reasonable interpretation consistent with the specification.” See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and MPEP § 2111. Applicants respectfully submit that the Office Action fails to understand the scope and content of the prior art.

For example, the Office Action acknowledges on Page 5 that SLIM fails to disclose one or more interfaces as recited in claim 1 that enable a user to create stability studies by specifying requirements that need to be fulfilled for the stability studies. However, the Office Action concludes on Page 4 without any explanation that such requirements are received as recited in claim 1 from a user through the Lab Work Request data entry forms outlined on Page 4, line 1 of SLIM. This is incorrect because SLIM explicitly states on Page 4, line 1 that the “Lab Work Request (LWR) data entry forms are interactive forms that allow the

user to enter results on screen” (emphasis added) for test associated with a protocol. SLIM states on Page 5, line 2 that the LWR forms are “dynamically build, thus, if you add a test to a protocol, the test immediately appears on the LWR.” Thus, SLIM does not disclose receiving input via the one or more first interfaces indicative of a set of requirements for a first stability study as recited in claim 1 because SLIM discloses the user utilizes the Lab Word Request data entry forms to enter test results. The data entry forms of SLIM used for test results are substantially different from the first interfaces recited in claim 1 used to specify requirements that need to be fulfilled for the stability studies.

In another example, the Office Action concludes that the same Lab Work Request data entry forms on Page 4, line 1 of SLIM also disclose one or more different interfaces recited in claim 1 that serve different purposes than the first interfaces. The second interfaces recited in claim 1 enable a user to create workflows associated with stages of stability studies. As recited in claim 1, input is received via the one or more second interfaces indicative of a set of workflows associated with a plurality of stages of the first stability study. Each workflow recited in claim 1 specifying a set of actions that need to be taken during each stage in the plurality of stages of the first stability study.

The Office Action fails to clearly articulate how entering the test protocol results into the LWR forms of SLIM can be interpreted as specifying workflows as recited in claim 1. As discussed above, the LWR forms are merely used to enter test results, and therefore SLIM fails to disclose receiving input indicative of a set of workflows associated with a plurality of stages of the first stability study as recited in claim 1. Additionally, the Office Action points to Stability which would allow database fields to have preset terms to facilitate information entry. However, the Office Action does not present facts or reasoning why the preset terms of Stability that facilitate information entry disclose input indicative of a set of workflows associated with a plurality of stages of the first stability study as recited in claim 1. Moreover, a database is typically considered to be a backend portion of a system and any user interfaces may be considered the front end. The terms, definitions, and logic of a front end user interface can be substantially different from the terms, definitions, and logic of a backend portion.

The Office Action also fails to provide reasoning how database fields with preset terms to facilitate information entry provide the second interfaces as recited in claim 1. Furthermore, the mere possibility that the database fields can have present terms does not disclose that a set of workflows associated with a plurality of stages of the first stability study are received as recited in claim 1 where each workflow specifies a set of actions that need to be taken during each stage in the plurality of stages of the first stability study. The Office Action fails to identify where SLIM or Stability disclose a user interface for creating a workflow as the second interfaces recited in claim 1.

In another example, the Office Action concludes that the same Lab Work Request data entry forms on Page 4, line 1 of SLIM also disclose one or more different interfaces recited in claim 1 that serve different purposes than the first interfaces and the second interfaces. As recited in claim 1, one or more third interfaces are displayed that enable a user to specify business rules for stability studies. The Office Action fails to clearly articulate how entering the test protocol results into the LWR forms of SLIM can be interpreted to specifying business rules as recited in claim 1. As discussed above, the LWR forms are merely used to enter test results, and therefore SLIM fails to disclose the third interfaces recited in claim 1.

Finally, the Office Action contradicts itself on Page 7 by concluding that SLIM and Stability disclose all the limitations of claim 1, but neither SLIM nor Stability disclose the steps of displaying the first, second, third, or fourth interfaces, and steps of receiving input via the first, second, third, or fourth interfaces. The Office Action suggests that simply repeating the providing and receiving steps with new input does not make the present application patentably distinct from SLIM because SLIM is capable of incorporating any number of variables through the use of Excel. However, this reasoning is incorrect because it suggests that SLIM merely may possibly incorporate any number of variables but not disclose the actual manner recited in claim 1.

Furthermore, the fact that Stability may allow database field definitions to be customized to meet user's requirements does not disclose that the display of the first, second, third, or fourth interfaces occurs as recited in claim 1 or that the "new input" recognized by the Office Action as recited in claim 1 is received via the appropriate corresponding interface.

Accordingly, Applicants respectfully submit that SLIM and Stability, either individually or in combination, fail to disclose each and every claim limitation as recited in claim 1. The Office Action fails to provide a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference. The Office Action further fails to provide a finding that the prior art had been improved in the same way as the claimed invention.

Applicants respectfully submit that independent claims 27 and 34 are allowable for at least a similar rationale as discussed above for the allowability of claim 1, and others. Applicants respectfully submit that dependent claims 2-12, 26-33, and 35 that depend directly and/or indirectly from the independent claims 1, 27, and 34 respectively, are also allowable for at least a similar rationale as discussed above for the allowability of the independent claims. Applicants further respectfully submit that the dependent claims recite additional features that make the dependent claims allowable for additional reasons.

Unless otherwise specified, amendments to the claims are made for the purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof.

While Applicants do not necessarily agree with the prior art rejections set forth in the Office Action, these amendments may be made to expedite issuance of the Application. Applicants reserve the right to pursue claims to subject matter similar to those pending before the present Amendment in co-pending or subsequent applications.

#### **Claim Rejections Under 35 U.S.C. § 101**

Applicants have clarified the language of claims 1-12, thus, Applicants respectfully traverse the rejections to claims 1-12 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 101.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

/Sean F. Parmenter, Reg. No. 53,437/  
Sean F. Parmenter  
Reg. No. 53,437

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
SFP:lls  
61597179 v1